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TITLE: Neuroepidemiologic Case Definition of Gulf War Illness from Neuroimaging and EEG in a Population-Representative Nested Case-Control Sample of Gulf War Veterans

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14. ABSTRACT The study will involve analysis of previously generated epidemiology data. Over the past 20 years a rigorously population-based epidemiologic study measured the standard list of symptoms of Gulf War illness (GWI) in a representative sample of 8,020 Gulf War-era veterans; scored all three major GWI case definitions—Factor, CDC and Kansas—with a full array of clinical diagnoses and laboratory findings and measures of symptom onset, duration, and severity; a subclassification of the CDC definition derived by factor analysis and validated by multiple objective measures; and with all analyses tested for differences due to effect modification by race and gender. The databases also contain the data for a hypothesis-driven 12-year longitudinal study of GWI natural history of symptoms and symptom descriptive characteristics in a subpopulation.					
15. SUBJECT TERMS Nothing listed					
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TABLE OF CONTENTS

	<u>Page No.</u>
1. Introduction	4
2. Keywords	4
3. Accomplishments	4
4. Impact	6
5. Changes/Problems	7
6. Products	9
7. Participants & Other Collaborating Organizations	13
8. Special Reporting Requirements	14
9. Appendices	14

1. INTRODUCTION:

The purpose of this project is to complete the statistical analyses and write scientific papers describing various aspects of Gulf War illness from a large database previously collected in the U.S. Military Health Survey, a national telephone interview survey in a random sample (N=8,020) of the 1991 U.S. military population.

2. KEYWORDS:

Survey research; population sample; disease description; longitudinal study; statistical analysis; disease symptoms; balance disorders; vertigo; disease prevalence; fertility; pregnancy complications; paternal exposure; delayed effects of prenatal exposure; spouses; offspring.

3. ACCOMPLISHMENTS:

The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

- 1: Administrative Preparation (IRB and HRPO approval) – Months 1-3 – completed at end of year 1
- 2: Analysis of symptoms, latency and severity – months 4-8
- 3: Analysis of balance disorders and vertigo attacks – months 9-13
- 4: Analysis of prevalence of clinical diagnoses – months 14-18
- 5: Analysis of chronic illness in veterans' spouses – months 19-23
- 6: Analyses of fertility and pregnancy outcomes in GW veterans and spouses – months 24-28
- 7: Analyses of cognitive disorders in prewar vs postwar offspring of GW-era veterans – mo. 29-33
- 8: Work with journal editors to get the papers published – months 9-36

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the

project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Following the UT Southwestern IRB's review of the proposed project in the 3rd quarter, in the 4th quarter we submitted the IRB's report to HRPO for their review. HRPO recently completed its review and at the very end of the 4th quarter HRPO informed us that our proposal has been approved. Thus, by the end of year 1, we have completed Major Task 1, Administrative Preparation (IRB and ORP/HRPO reviews).

What opportunities for training and professional development has the project provided?

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to Report.

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to Report.

If this is the final report, state “Nothing to Report.”

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

In the 1st quarter of Year 2 we plan to organize the large SAS database collected in the U.S. Military Health Survey and make it ready to analyze for the Major Tasks 2 through 7. When the database has been organized, we will begin analysis of Gulf War veterans’ symptoms, latency and severity for Major Task 2. As time allows we may also work on Major Tasks 5 and 6, which are of interest to an ongoing review of this subject by the most recently constituted committee of the National Academy of Medicine’s project on Gulf War Veterans and Health.

- 4. IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to Report.

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report.

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report.

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report.

- 5. CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to Report.

Actual or anticipated problems or delays and actions or plans to resolve them

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

The only problem is accelerating our analytic production schedule to make up time lost in the first two quarters when we were unable to begin work as soon as the project was approved for funding.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

The study is financially in good shape for completing the proposed major tasks. Although we lost the first two quarters, we did not spend any of the funds during that period so that we have sufficient funds remaining to increase staff time to accelerate the analytic production so as to complete the work within the funding period, or request a no-cost extension at the end.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to Report.

Significant changes in use or care of vertebrate animals.

Not applicable.

Significant changes in use of biohazards and/or select agents

Not applicable.

6. PRODUCTS: List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”

- **Publications, conference papers, and presentations**

Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted,*

awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

Nothing to Report.

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report.

Other publications, conference papers, and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to Report.

- **Website(s) or other Internet site(s)**

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report.

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

Nothing to Report.

- **Inventions, patent applications, and/or licenses**

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report.

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*

- *biospecimen collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change."

<i>Name:</i>	<i>Robert W. Haley, MD</i>
<i>Project Role:</i>	<i>PI</i>
<i>Researcher Identifier:</i>	<i>ORCHID ID: orcid.org/0000-0001-8849-9579</i>
	<i>Researcher ID: P-9026-2014</i>
	<i>Scopus Author ID: 7005591662</i>
<i>Nearest person month worked:</i>	<i>1</i>
<i>Contribution to Project:</i>	<i>Worked with the UT Southwestern IRB to facilitate the IRB's review of the history of the project and its IRB approvals.</i>
<i>Funding Support:</i>	<i>No other funding support.</i>
<i>Name:</i>	<i>Deborah Modesette</i>
<i>Project Role:</i>	<i>Project coordinator</i>
<i>Researcher Identifier:</i>	<i>None</i>
<i>Nearest person month worked:</i>	<i>1</i>
<i>Contribution to Project:</i>	<i>Worked with the UT Southwestern IRB to facilitate the IRB's review of the history of the project and its IRB approvals.</i>
<i>Funding Support:</i>	<i>No other support</i>

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to Report.

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:

Organization Name:

Location of Organization: (if foreign location list country)

Partner’s contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner’s facilities for project activities);*
- *Collaboration (e.g., partner’s staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner’s staff use each other’s facilities, work at each other’s site); and*
- *Other.*

Nothing to Report.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

QUAD CHARTS: N/A

9. APPENDICES: N/A